

Preliminary Classification:  
Proposed Class:  
Subclass:

NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.'" M.P.E.P. Section 601, 7th ed.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application  
Assistant Commissioner for Patents  
Washington, D.C. 20231

**CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) AND 1.10\***

*(When using Express Mail, the Express Mail label number is **mandatory**;  
Express Mail certification is optional)*

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

☐ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

37 C.F.R. Section 1.8(a)

37 C.F.R. Section 1.10\*

☐ with sufficient postage as first class mail.

☒ as "Express Mail Post Office to Address"  
Mailing Label No. EL 789782945 US  
(**mandatory**)

**TRANSMISSION**

☐ transmitted by facsimile to the Patent and Trademark Office (703) \_\_\_\_\_

Date: November 2, 2001

Signature

John B. Alexander, Ph.D.

(type or print name of person certifying)

**\*WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. Section 1.10(b).  
"Since the filing of correspondence under [Section] 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

11/02/01



12-05-01

A

## NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): HANDA, Hiroshi  
KAWAGUCHI, Haruma

**WARNING:** 37 C.F.R. Section 1.41(a)(1) points out:

"(a) A patent is applied for in the name or names of the actual inventor or inventors.

(1) The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by Section 1.63, except as provided for in Section 1.53(d)(4) and Section 1.63(d). If an oath or declaration as prescribed by Section 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to Section 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in Section 1.17(i) is filed supplying or changing the name or names of the inventor or inventors."

For (title): DRUG-IMMOBILIZED PARTICLES AND A PROCESS OF PURIFYING PROTEINS

### 1. Type of Application

This new application is for a(n)

(check one applicable item below)

- ☒ [X] Original (nonprovisional)  
☐ [ ] Design  
☐ [ ] Plant

**WARNING:** Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4), unless the International Application is being filed as a divisional, continuation or continuation-in-part application.

**WARNING:** Do not use this transmittal for the filing of a provisional application.

**NOTE:** If one of the following 3 items apply, then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.

- ☒ [X] Divisional.  
☐ [ ] Continuation.  
☐ [ ] Continuation-in-part (C-I-P).

### 2. Benefit of Prior U.S. Application(s) (35 U.S.C. Sections 119(e), 120, or 121)

**NOTE:** A nonprovisional application may claim an invention disclosed in one or more prior filed copending nonprovisional



applications or copending international applications designating the United States of America. In order for a nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application designating the United States of America, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. Section 112. Each prior application must also be:

(i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or

(ii) Complete as set forth in Section 1.51(b); or

(iii) Entitled to a filing date as set forth in Section 1.53(b) or Section 1.53(d) and include the basic filing fee set forth in Section 1.16; or

(iv) Entitled to a filing date as set forth in Section 1.53(b) and have paid therein the processing and retention fee set forth in Section 1.21(l) within the time period set forth in Section 1.53(f).

37 C.F.R. Section 1.78(a)(1).

**NOTE** If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

**WARNING:** If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

**WARNING:** When the last day of pendency of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, any nonprovisional application claiming benefit of the provisional application **must** be filed prior to the Saturday, Sunday, or Federal holiday within the District of Columbia. See 37 C.F.R. Section 1.78(a)(3).

[X] The new application being transmitted claims the benefit of prior U.S. application(s). Enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

### 3. Papers Enclosed

A. Required for Filing Date under 37 C.F.R. Section 1.53(b) (Regular) or 37 C.F.R. Section 1.153 (Design) Application

\_\_64\_\_ Pages of Specification

\_\_3\_\_ Pages of Claims

\_\_15\_\_ Sheets of Drawing

**WARNING:** *DO NOT* submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to Section 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. For comments on proposed then-new 37 C.F.R. 1.84, see Notice of March 9, 1988 . (1990 O.G. 57-62).

**NOTE:** "Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawing a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page. . ." 37 C.F.R. Section 1.84(c)).

(complete the following, if applicable)

☐ The enclosed drawing(s) are photograph(s), and there is also attached a "PETITION TO ACCEPT PHOTOGRAPH(S) AS DRAWING(S)." 37 C.F.R. Section 1.84(b).

☒ Formal

☐ Informal

**B. Other Papers Enclosed**

\_\_\_\_ Pages of declaration and power of attorney

  1   Pages of Abstract

\_\_\_\_ Other

**4. Additional Papers Enclosed**

☐ Amendment to claims

☐ Cancel in this applications claims \_\_\_\_\_ before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)

☐ Add the claims shown on the attached amendment. (Claims added have been numbered consecutively following the highest numbered original claims.)

☒ Preliminary Amendment

☐ Information Disclosure Statement (37 C.F.R. Section 1.98)

☐ Form PTO-1449 (PTO/SB/08A and 08B)

☐ Citations

☐ Declaration of Biological Deposit

☒ Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.

☐ Authorization of Attorney(s) to Accept and Follow Instructions from Representative

☐ Special Comments

☐ Other

## 5. Declaration or Oath (including power of attorney)

**NOTE:** A newly executed declaration is not required in a continuation or divisional application provided the prior nonprovisional application contained a declaration as required, the application being filed is by all or fewer than all the inventors named in the prior application, there is no new matter in the application being filed, and a copy of the executed declaration filed in the prior application (showing the signature or an indication thereon that it was signed) is submitted. The copy must be accompanied by a statement requesting deletion of the names of person(s) who are not inventors of the application being filed. If the declaration in the prior application was filed under Section 1.47 then a copy of that declaration must be filed accompanied by a copy of the decision granting Section 1.47 status or, if a nonsigning person under Section 1.47 has subsequently joined in a prior application, then a copy of the subsequently executed declaration must be filed. See 37 C.F.R. Section 1.63(d)(1)-(3).

**NOTE:** A declaration filed to complete an application must be executed, identify the specification to which it is directed, identify each inventor by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and the residence, post office address and country of citizenship of each inventor, and state whether the inventor is a sole or joint inventor. 37 C.F.R. Section 1.63(a)(1)-(4).

**NOTE:** A The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by Section 1.62, except as provided for in Section 1.53(d)(4) and Section 1.63(d). If an oath or declaration as prescribed by Section 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to Section 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in Section 1.17(I) is filed supplying or changing the name or names of the inventor or inventors. 37 C.F.R. Section 1.41(a)(1).

☒ Enclosed

Executed by

(check **all** applicable boxes)

☒ inventor(s).

☐ legal representative of inventor(s). 37 C.F.R. Section 1.42 or 1.43.

☐ joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.

☐ This is the petition required by 37 C.F.R. Section 1.47 and the statement required by 37 C.F.R. Section 1.47 is also attached. See item 13 below for fee.

☐ Not Enclosed.

**NOTE:** Where the filing is a completion in the U.S. of an International Application, or where the completion of the U.S. application contains subject matter in addition to the International Application, the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.

☐ Application is made by a person authorized under 37 C.F.R. 1.41 on behalf of all the above named inventor(s).

(The declaration or oath, along with the surcharge required by 37 C.F.R. Section 1.16(e),

can be filed subsequently).

- ☐ Showing that the filing is authorized.  
(not required unless called into question. 37 C.F.R. Section 1.41(d))

## 6. Inventorship Statement

**WARNING:** If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.

The inventorship for all the claims in this application are:

- ☒ The same.

or

- ☐ Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,  
☐ is submitted.  
☐ will be submitted.

## 7. Language

**NOTE:** An application including a signed oath or declaration may be filed in a language other than English. An English translation of the non-English language application and the processing fee of \$130.00 required by 37 C.F.R. Section 1.17(k) is required to be filed with the application, or within such time as may be set by the Office. 37 C.F.R. Section 1.52(d).

- ☒ English  
☐ Non-English

- ☐ The attached translation includes a statement that the translation is accurate. 37 C.F.R. Section 1.52(d).

## 8. Assignment

- ☐ An assignment of the invention to \_\_\_\_\_

- ☐ is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.  
☒ will follow.

**NOTE:** "If an assignment is submitted with a new application, send two separate letters-one for the application and one for the assignment" Notice of May 4, 1990 (1114 O.G. 77-78).

**WARNING:** A newly executed "STATEMENT UNDER 37 C.F.R. Section 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64.

## 9. Certified Copy

Certified copy(ies) of application(s)		
Japan	18827/1996	February 5, 1996
Japan	266711/1996	September 17, 1996
Country	Appln. no.	Filed

from which priority is claimed

- ☐ is (are) attached.  
☐ will follow.

**NOTE:** The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 C.F.R. Section 1.55(a) and 1.63.

**NOTE:** This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. 120 is itself entitled to priority from a prior foreign application, then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

## 10. Fee Calculation (37 C.F.R. Section 1.16)

A. ☒ Regular application

### CLAIMS AS FILED

Claims	Number Filed	Basic Fee Allowance	Number Extra	Rate	Basic Fee 37 C.F.R. Section 1.16(a) <b>\$740.00</b>
Total Claims (37 C.F.R. Section .16(c))	1	- 20 =	0 x	\$18.00	
Independent Claims (37 C.F.R. Section 1.16(b))	1	- 3 =	0 x	\$84.00	
Multiple Dependent Claim(s), if any (37 C.F.R. Section 1.16(d))		+	\$280.00		

- ☒ Amendment cancelling extra claims is enclosed.  
☐ Amendment deleting multiple-dependencies is enclosed.  
☒ Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 C.F.R. Section 1.16(d).

Filing Fee Calculation \$ 740.00

- B. ☐ Design application  
(\$330.00--37 C.F.R. Section 1.16(f))

Filing Fee Calculation \$ \_\_\_\_\_

- C. ☐ Plant application  
(\$510.00--37 C.F.R. Section 1.16(g))

Filing Fee Calculation \$ \_\_\_\_\_

#### 11. Small Entity Statement(s)

- ☒ Statement(s) that this is a filing by a small entity under 37 C.F.R. Section 1.9 and 1.27 is (are) attached.

**WARNING:** "Status as a small entity must be specifically established in each application or patent in which the status is available and desired. Status as a small entity in one application or patent does not affect any other application or patent, including applications or patents which are directly or indirectly dependent upon the application or patent in which the status has been established. The refiling of an application under Section 1.53 as a continuation, division, or continuation-in-part (including a continued prosecution application under Section 1.53(d)), or the filing of a reissue application requires a new determination as to continued entitlement to small entity status for the continuing or reissue application. A nonprovisional application claiming benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) of a prior application, or a reissue application may rely on a statement filed in the prior application or in the patent if the nonprovisional application or the reissue application includes a reference to the statement in the prior application or in the patent or includes a copy of the statement in the prior application or in the patent and status as a small entity is still proper and desired. The payment of the small entity basic statutory filing fee will be treated as such a reference for purposes of this Section." 37 C.F.R. Section 1.28(a)(2).

**WARNING:** "Small entity status must not be established when the person or persons signing the . . . statement can unequivocally make the required self-certification." M.P.E.P. Section 509.03, 6th ed., rev. 2, July 1996 (emphasis added).

(complete the following, if applicable)

- ☒ Status as a small entity was claimed in prior application  
09/440,597, filed on November 15, 1999 from which  
benefit is being claimed for this application under:

35 U.S.C. Section ☐ 119(e),



☒ 120,  
☐ 121,  
☐ 365(c),

and which status as a small entity is still proper and desired.

☒ A copy of the statement in the prior application is included.

Filing Fee Calculation (50% of A, B or C above) \$ 370.00

NOTE: Any excess of the full fee paid will be refunded if a small entity status is established refund request are filed within 2 months of the date of timely payment of a full fee. The two-month period is not extendable under Section 1.136. 37 C.F.R. Section 1.28(a).

**12. Request for International-Type Search (37 C.F.R. Section 1.104(d))**

*(complete, if applicable)*

☐ Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

**13. Fee Payment Being Made at This Time**

☐ Not Enclosed

☐ No filing fee is to be paid at this time.  
*(This and the surcharge required by 37 C.F.R. Section 1.16(e) can be paid subsequently.)*

☒ Enclosed

☒ Filing fee \$ 370.00

☐ Recording assignment  
(\$40.00; 37 C.F.R. Section 1.21(h))  
(See attached "COVER SHEET FOR  
ASSIGNMENT ACCOMPANYING NEW  
APPLICATION.") \$ \_\_\_\_\_

☐ Petition fee for filing by other  
than all the inventors or person  
on behalf of the inventor where  
inventor refused to sign or cannot  
be reached  
(\$130.00; 37 C.F.R. Sections 1.47 and 1.17(i))\$

☐ For processing an application with a

specification in a non-English language  
(\$130.00; 37 C.F.R. Sections 1.52(d) and 1.17(k))\$

☐ Processing and retention fee  
(\$130.00; 37 C.F.R. Sections 1.53(d) and 1.21(l))\$

☐ Fee for international-type search report  
(\$40.00; 37 C.F.R. Section 1.21(e)) \$

*NOTE: 37 C.F.R. Section 1.21(l) establishes a fee for processing and retaining any application that is abandoned for failing to complete the application pursuant to 37 C.F.R. Section 1.53(f) and this, as well as the changes to 37 C.F.R. Section 1.53 and 1.78(a)(1), indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid, or the processing and retention fee of Section 1.21(l) must be paid, within 1 year from notification under Section 53(f).*

Total Fees Enclosed \$ 370.00

#### 14. Method of Payment of Fees

- ☒ Check in the amount of \$ 370.00 .
- ☐ Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_.  
A duplicate of this transmittal is attached.

*NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. Section 1.22(b).*

#### 15. Authorization to Charge Additional Fees

**WARNING:** If no fees are to be paid on filing, the following items should not be completed.

**WARNING:** Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

- ☐ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. \_\_\_\_\_.
- ☐ 37 C.F.R. Section 1.16(a), (f) or (g) (filing fees)
- ☐ 37 C.F.R. Section 1.16(b), (c) and (d) (presentation of extra claims)

*NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. Section 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.*

- ☐ 37 C.F.R. Section 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

☐ 37 C.F.R. Section 1.17(a)(1)-(5) (extension fees pursuant to Section 1.136(a).

☐ 37 C.F.R. Section 1.17 (application processing fees)

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under Section 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in Section 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. Section 1.136(a)(3).

☐ 37 C.F.R. Section 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. Section 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. Section 1.311(b)).

NOTE: 37 C.F.R. Section 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . . issue fee." From the wording of 37 C.F.R. Section 1.28(b), (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

## 16. Instructions as to Overpayment

NOTE: ". . . Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. Section 1.26(a).

☒ Credit Account No. 04-1105.

☐ Refund

Date: November 2, 2001

  
SIGNATURE OF PRACTITIONER

Reg. No. 48,399

John B. Alexander

(type or print name of practitioner)

Tel. No.: (617) 439-4444

Dike, Bronstein, Roberts & Cushman  
Intellectual Property Practice Group  
**EDWARDS & ANGELL, LLP**  
P. O. Box 9169  
Boston, MA 02209

☒ **Incorporation by reference of added pages**

*(check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)*

☒ Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

Number of pages added 5

☐ Plus Added Pages for Papers Referred to in Item 4 Above

Number of pages added \_\_\_\_\_

☐ Plus added pages deleting names of inventor(s) named on prior application(s) who is/are no longer inventor(s) of the subject matter claimed in this application.

Number of pages added \_\_\_\_\_

☐ Plus "Assignment Cover Letter Accompanying New Application"

Number of pages added \_\_\_\_\_

Added page 5

(Added Page(s) for Special Comments for New Application Transmittal)

# **ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**

NOTE: See 37 CFR 1.78.

## **17. Relate Back**

**WARNING:** If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

*(complete the following, if applicable)*

☒ Amend the specification by inserting, before the first line, the following sentence:

### **A. 35 U.S.C. 119(e)**

NOTE: "Any nonprovisional application claiming the benefit of one or more prior filed copending provisional applications must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior provisional application, identifying it as a provisional application, and including the provisional application number (consisting of series code and serial number)." 37 C.F.R. § 1.78(a)(4).

☐ "This application claims the benefit of U.S. Provisional Application(s) No(s).:

**APPLICATION NO(S).:**

**FILING DATE**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_/\_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### **B. 35 U.S.C. 120, 121 and 365(c)**

NOTE: "Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. . . . Cross-references to other related applications may be made when appropriate." (See § 1.14(a)). 37 C.F.R. § 1.78(a)(2).

☒ "This application is a

☐ continuation

☐ continuation-in-part

☒ divisional

of copending application(s)

☒ application number 09/440,597 filed on November 15, 1999

☐ International Application \_\_\_\_\_ filed on \_\_\_\_\_ and which designated the U.S.”

NOTE: The proper reference to a prior filed PCT application that entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application that designated the U.S.

NOTE: (1) Where the application being transmitted adds subject matter to the International Application, then the filing can be as a continuation-in-part or (2) if it is desired to do so for other reasons then the filing can be as a continuation.

NOTE: The deadline for entering the national phase in the U.S. for an international application was clarified in the Notice of April 28, 1987 (1079 O.G. 32 to 46) as follows:

“The Patent and Trademark Office considers the International application to be pending until the 22nd month from the priority date if the United States has been designated and no Demand for International Preliminary Examination has been filed prior to the expiration of the 19th month from the priority date and until the 32nd month from the priority date if a Demand for International Preliminary Examination which elected the United States of America has been filed prior to the expiration of the 19th month from the priority date, provided that a copy of the international application has been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively. If a copy of the international application has not been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively, the international application becomes abandoned as to the United States 20 or 30 months from the priority date respectively. These periods have been placed in the rules as paragraph (h) of § 1.494 and paragraph (i) of § 1.495. A continuing application under 35 U.S.C. 365(c) and 120 may be filed anytime during the pendency of the international application.”

☒ “The nonprovisional application designated above, namely application 08 / 795,927, filed February 5, 1997, claims the benefit of U.S. Application(s) No(s).:

APPLICATION NO(S):

FILING DATE

\_\_\_\_\_/\_\_\_\_\_  
\_\_\_\_\_/\_\_\_\_\_  
\_\_\_\_\_/\_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

☒ Where more than one reference is made above please combine all references into one sentence.

#### 18. Relate Back—35 U.S.C. 119 Priority Claim for Prior Application

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 17B, in turn itself claim(s) foreign priority(ies) as follows:

Country	Application No.	Filed
Japan	18827/1996	February 5, 1996
Japan	266711/1996	September 17, 1996

The certified copy(ies) has (have)

☒ been filed in prior application 08/795,297, which was filed on February 5, 1997.

☐ is (are) attached.

**WARNING:** *The certified copy of the priority application that may have been communicated to the PTO by the International Bureau may not be relied on without any need to file a certified copy of the priority application in the continuing application. This is so because the certified copy of the priority application communicated by the International Bureau is placed in a folder and is not assigned a U.S. serial number unless the national stage is entered. Such folders are disposed of if the national stage is not entered. Therefore, such certified copies may not be available if needed later in the prosecution of a continuing application. An alternative would be to physically remove the priority documents from the folders and transfer them to the continuing application. The resources required to request transfer, retrieve the folders, make suitable record notations, transfer the certified copies, enter and make a record of such copies in the Continuing Application are substantial. Accordingly, the priority documents in folders of international applications that have not entered the national stage may not be relied on. Notice of April 28, 1987 (1079 O.G. 32 to 46).*

## 19. Maintenance of Copendency of Prior Application

**NOTE:** *The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).*

### A. ☒ Extension of time in prior application

*(This item **must** be completed and the papers filed in the prior application, if the period set in the prior application has run.)*

☒ A petition, fee and response extends the term in the pending **prior** application until November 2, 2001.

☒ A **copy** of the petition filed in prior application is attached.

### B. ☐ Conditional Petition for Extension of Time in Prior Application

*(complete this item, if previous item not applicable)*

☐ A conditional petition for extension of time is being filed in the pending **prior** application.

☐ A **copy** of the conditional petition filed in the prior application is attached.

## 20. Further Inventorship Statement Where Benefit of Prior Application(s) Claimed

*(complete applicable item (a), (b) and/or (c) below)*

(a) ☒ This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) in this application are

☒ the same.

☐ less than those named in the prior application. It is requested that the following inventor(s) identified for the prior application be deleted:

---

*(type name(s) of inventor(s) to be deleted)*

(b) ☐ This application discloses and claims additional disclosure by amendment and a new declaration or oath is being filed. With respect to the prior application, the inventor(s) in this application are

☐ the same.

☐ the following additional inventor(s) have been added:

---

*(type name(s) of inventor(s) to be deleted)*

(c) ☒ The inventorship for all the claims in this application are

☒ the same.

☐ not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made

☐ is submitted.

☐ will be submitted.

## **21. Abandonment of Prior Application (if applicable)**

☐ Please abandon the prior application at a time while the prior application is pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so as to make this application copending with said prior application.

**NOTE:** According to the Notice of May 13, 1983 (103, TMOG 6-7), the filing of a continuation or continuation-in-part application is a proper response with respect to a petition for extension of time or a petition to revive and should include the express abandonment of the prior application conditioned upon the granting of the petition and the granting of a filing date to the continuing application.

## **22. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment**

**WARNING:** "The claims of a new application may be finally rejected in the first Office action in those situations where (1) the new application is a continuing application of, or a substitute for, an earlier application, and (2) all the claims of the new application (a) are drawn to the same invention claimed in the earlier application, and (b) would have been



*properly finally rejected on the grounds of art of record in the next Office action if they had been entered in the earlier application." MPEP, § 706.07(b).*

**NOTE:** *Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary.*

*(check the next item, if applicable)*

☐ There is provided herewith a Petition To Suspend Prosecution for the Time Necessary to File An Amendment (New Application Filed Concurrently)

**23. Small Entity (37 CFR § 1.28(a))**

☒ Applicant has established small entity status by the filing of a statement in parent application No. 09/440,597.

☒ A copy of the statement previously filed is included.

**WARNING:** See 37 CFR § 1.28(a).

**24. NOTIFICATION IN PARENT APPLICATION OF THIS FILING**

☐ A notification of the filing of this  
*(check one of the following)*

- ☐ continuation
- ☐ continuation-in-part
- ☐ divisional

is being filed in the parent application, from which this application claims priority under 35 U.S.C. § 120.

Practitioner's Docket No. 47115 CIP DIV2 (71526)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: H. HANDA, et al.

Application No.: Not yet assigned

Group No.: not yet assigned

Filed: Herewith

Examiner: not yet assigned

For: DRUG-IMMOBILIZED PARTICLES AND A PROCESS OF PURIFYING PROTEINS

Box Sequence

Assistant Commissioner for Patents

Washington, D.C. 20231

SUBMISSION OF "SEQUENCE LISTING," COMPUTER READABLE COPY,  
AND/OR AMENDMENT PERTAINING THERETO

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10\*

(When using Express Mail, the Express Mail label number is *mandatory*;  
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

37 C.F.R. § 1.8(a)

37 C.F.R. § 1.10\*


☐ with sufficient postage as first class mail.

☒ as "Express Mail Post Office to Address"  
Mailing Label No. EL 789782945 US  
\_ (mandatory)

TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.

Signature



Date: November 2, 2001

John B. Alexander, Ph.D.

(type or print name of person certifying)

**\*WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be

**FOR BIOTECHNOLOGY INVENTION CONTAINING NUCLEOTIDE  
AND/OR AMINO ACID SEQUENCE**

*(check and complete this item, if applicable)*

1. ☐ This replies to the Office Letter DATED \_\_\_\_\_.

*NOTE: If these papers are filed before the office letter issues, adequate identification of the original papers should be made, e.g., in addition to the name of the inventor and title of invention, the filing date based on the "Express Mail" procedure, the serial number from the return post card or the attorney's docket number added.*

- ☐ A copy of the Office Letter is enclosed.

**IDENTIFICATION OF PERSON MAKING STATEMENT**

2. I, John B. Alexander, Ph.D.  
*(type or print name of person signing below)*

state the following:

**ITEMS BEING SUBMITTED**

3. Submitted herewith is/are

*(check each item as applicable)*

- A. ☐ "Sequence Listing(s)" for the nucleotide and/or amino acid sequence(s) in this application. Each "Sequence Listing" is assigned a separate identifier as required in 37 C.F.R. § 1.821(c) and 37 C.F.R. §§ 1.822 and 1.823.
- B. ☐ An amendment to the description and/or claims, wherein reference is made to the sequence by use of the assigned identifier, as required in 37 C.F.R. § 1.821(d).
- C. ☐ A copy of each "Sequence Listing" submitted for this application in computer readable form, in accordance with the requirements of 37 C.F.R. §§ 1.821(e) and 1.824.
- D. ☒ Please transfer to this application, in accordance with 37 C.F.R. § 1.821(e), the computer readable copy(ies) from applicant's other application identified as follows:

In re application of: H. Handa et al.

Application No.: 09/440,597

Filed: November 15, 1999

Group No.: 1651

Examiner: D. Naff

For: DRUG-IMMOBILIZED PARTICLES AND A PROCESS OF PURIFYING PROTEINS

The Computer readable form(s) of applicant's other application corresponds to the "Sequence Identifier(s)" of the application as follows:

Computer Readable Form  
(other application)

“Sequence Identifier”  
(this application)

NOTE: *“If the computer readable form of a new application is to be identical with the computer readable form of another application of the applicant on file in the Office, reference maybe made to the other application and computer readable form in lieu of filing a duplicate computer readable form in the new application. The new application shall be accompanied by a letter making such reference to the other application and computer readable form, both of which shall be completely identified.” 37 C.F.R. § 1.821(e).*

E. ☒ A statement that the content of each “Sequence Listing” submitted and each computer readable copy are the same, as required in 37 C.F.R. § 1.821(g).

☐ Because the statement is not made by a person registered to practice before the Office, the Statement is verified as required in 37 C.F.R. § 1.821(b).

F. ☐ Because this submission is made in fulfilling the requirement under 37 C.F.R. § 1.821(g), a statement that the submission includes no new matter.

☐ Because the statement is not made by a person registered to practice before the Office, the statement is verified, as required in 37 C.F.R. § 1.821(g).

**STATEMENT THAT “SEQUENCE LISTING”  
AND COMPUTER READABLE COPY ARE THE SAME  
AND/OR THAT PAPERS SUBMITTED INCLUDES NO NEW MATTER**

4. I hereby state:

*(complete applicable item A and/or B)*

A. ☒ Each computer readable form submitted in this application, including those forms requested to be transferred from applicant’s other application, is the same as the “Sequence Listing” to which it is indicated to relate.

B. ☐ All papers accompanying this submission, or for which a request for transfer from applicants' other application, introduce no new matter.

## STATUS

5. Applicant is

☒ a small entity. A statement:

☒ is attached.

☒ was already filed.

☐ other than a small entity.

## EXTENSION OF TERM

### 6. Extension of Term

NOTE: *"Extension of Time in Patent Cases (Supplement Amendments) If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.*

*If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run." Notice of Dec. 10, 1985 (1061 O.G. 34-35).*

NOTE: See 37 C.F.R. § 1.645 for extensions of time in interference proceedings and 37 C.F.R. § 1.550(c) for extensions of time in reexamination proceedings.

### 7. The proceedings herein are for a patent application and the provisions of 37 C.F.R. § 1.136 apply.

*(complete (a) or (b) as applicable)*

- (a) ☐ Applicant petitions for an extension of time under 37 C.F.R. § 1.136 (fees: 37 C.F.R. § 1.17(a)(1)-(4)) for the total number of months checked below:

	<u>Extension (months)</u>	<u>Fee for other than small entity</u>	<u>Fee for small entity</u>
<input type="checkbox"/>	one month	\$110.00	\$ 55.00
<input type="checkbox"/>	two months	\$390.00	\$ 195.00
<input type="checkbox"/>	three months	\$890.00	\$ 445.00
<input type="checkbox"/>	four months	\$1,390.00	\$ 695.00

Fee \$ \_\_\_\_\_

If an additional extension of time is required, please consider this a petition therefor.

*(check and complete the next item, if applicable)*

- ☐ An extension for \_\_\_\_\_ months has already been secured, and the fee paid therefor of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ \_\_\_\_\_

**OR**

- (b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the

need for a petition and fee for extension of time.

### FEE PAYMENT

8. ☐ Attached is a check in the sum of \$ \_\_\_\_\_.

☐ Charge Account No. \_\_\_\_\_ the sum of \$ \_\_\_\_\_.  
A duplicate of this transmittal is attached.

### FEE DEFICIENCY

9.

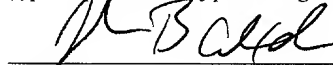
*NOTE: If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, 1065 O.G. 31-33.*

10. ☒ If any additional extension and/or fee is required, charge Account No. 04-1105.

### SIGNATURE(s)

John B. Alexander, Ph.D.

(type or print name of person signing statement)



Signature

November 2, 2001

DIKE, BRONSTEIN, ROBERTS & CUSHMAN  
Intellectual Property Practice Group  
EDWARDS & ANGELL, LLP  
P. O. Box 9169, Boston, MA 02209

(If applicable)

Tel. No.: (617) 439-4444  
Fax No.: (617) 439-4170  
Customer No. 21874

- ☐ Inventor
  - ☐ Assignee of complete interest
  - ☐ Person authorized to sign on behalf of assignee
  - ☒ Practitioner of record
  - ☐ Filed under Rule 34(a)
  - ☒ Registration No. 48,399
  - ☐ Other
- (specify identity of person signing)

(complete the following, if applicable)

\_\_\_\_\_  
(type name of assignee)

\_\_\_\_\_  
Address of assignee


\_\_\_\_\_  
Title of person authorized to sign on behalf of assignee

A "STATEMENT UNDER 37 C.F.R. 3.73(b)" is attached.

Assignment recorded in PTO on \_\_\_\_\_  
Reel \_\_\_\_\_ Frame \_\_\_\_\_

Reg. No. P-48,399  
Reg. No. 40,927

Customer No. 21874  
Tel. No. (617) 439-4444

  
\_\_\_\_\_  
**SIGNATURE OF PRACTITIONER**  
John B. Alexander, Ph.D.  
Robert L. Buchanan, Ph. D.  
(type or print name of practitioner)

Dike, Bronstein, Roberts & Cushman  
Intellectual Property Practice Group  
**EDWARDS & ANGELL, LLP**  
P. O. Box 9169  
Boston, MA 02209